# PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

ASTRAZENECA
Global Intellectual Property
S-151 85 Södertälje
SUEDE

PCT -2 DEC 2005

| CODE | DATE | NTD |
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ANKOM 30 NOV 2005 GIPS

DATA ENTERED

FINAL CHECK

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing *(day/month/year)* 29.11.2005

Applicant's or agent's file reference
101245-1 WO

**IMPORTANT NOTIFICATION**

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/GB2004/004202 | 04.10.2004 | 07.10.2003 |

Applicant
ASTRAZENECA AB ET AL.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
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Authorized Officer

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Form PCT/IPEA/416 (January 2004)

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference<br>101245-1 WO | **FOR FURTHER ACTION** | See Form PCT/IPEA/416 |
|---|---|---|
| International application No.<br>PCT/GB2004/004202 | International filing date *(day/month/year)*<br>04.10.2004 | Priority date *(day/month/year)*<br>07.10.2003 |
| International Patent Classification (IPC) or national classification and IPC<br>A61M15/00, B65D83/14, B65B31/00, B29C71/00 | | |
| Applicant<br>ASTRAZENECA AB ET AL. | | |

| CODE | DATE | NTD |
|---|---|---|
| | | |

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1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the opinion |
| ☐ | Box No. II | Priority |
| ☒ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☒ | Box No. VII | Certain defects in the international application |
| ☒ | Box No. VIII | Certain observations on the international application |

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 07.06.2005 | 29.11.2005 |


Name and mailing address of the international preliminary examining authority:

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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/004202

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

| | |
|---|---|
| **Description, Pages** | |
| 1-8 | as originally filed |
| **Claims, Numbers** | |
| 1-11 | as originally filed |
| **Drawings, Sheets** | |
| 1/2-2/2 | as originally filed |

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 11

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 11

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

| | | |
|---|---|---|
| the written form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |
| the computer readable form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/004202

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 5,10 |
| | No: | Claims | 1-4,6-9 |
| Inventive step (IS) | Yes: | Claims | 10 |
| | No: | Claims | 1-9 |
| Industrial applicability (IA) | Yes: | Claims | 1-10 |
| | No: | Claims | |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

## Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

## Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V.**

1. The following documents are referred to in this communication:
   D1 : US 2002/048552 A1 (GARRILL KARL ANDREW ET AL) 25 April 2002 (2002-04-25)
   D2 : WO 03/055547 A (GLAXO GROUP LTD ; TAYLOR ANTHONY JAMES (GB)) 10 July 2003 (2003-07-10)
   D3 : WO 01/00262 A (CAMBRIDGE CONSULTANTS ; EASON STEPHEN WILLIAM (GB); HARMER QUENTIN JOH) 4 January 2001 (2001-01-04)

2. INDEPENDENT CLAIM 1

   1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parenthesis applying to this document): A process for the preparation of a dry powder inhaler (34) which comprises exposing, during manufacture, a dry powder inhaler (34) optionally filed with a powder formulation, or one or more components thereof, to a gas at low pressure.

   2. Also document D3 discloses all the features of claim 1.

3. DEPENDENT CLAIMS 2-9

Dependent claims 2-9 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

   1. In particular:

- the features of claims 2-4, 6-9 are disclosed in combination with the features of claim 1 in D1. Therefore, the subject matter of claims 2-4, 6-9 is not new.
- the features of claim 5 are disclosed for the same purpose as in the present application in document D2. Therefore, the subject matter of claim 5 does not involve an inventive step.

4. INDEPENDENT CLAIM 10

1. Document D1, which is considered to represent the most relevant state of the art, discloses (the references in parenthesis applying to this document):

A process comprising:
- placing one or more inhaler (34) components, or a complete inhaler optionally filed with a powder formulation in a chamber (22),
- reducing the pressure of gas in the chamber (22),
- returning the pressure to atmospheric pressure.

From this, the subject-matter of independent claim 10 differs in that:
the process is for reducing electrostatic charges.

1. The subject-matter of claim 10 is therefore novel (Article 33(2) PCT)

The problem to be solved by the present invention may be regarded as:
to give high performance characteristics of the inhaler, i.e. dose uniformity.

2. The solution to this problem proposed in claim 10 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

To decompress a chamber in order to reduce electrostatic charges from an inhaler has not been addressed in the prior art.

5. The process described in claims 1 and 10 is industrially applicable, and therefore the requirements of Article 33(4) PCT are met.

1. Dependent claims 2-9 are preferred embodiments of claim 1. In view of that, claims 2 to 10 meet the requirements of Article 33(4) PCT as well.

**Re Item VII.**

6. Independent claims 1 and 10 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

7. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

8. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

**Re Item VIII.**

9. Although claims 1 and 10 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

10. It is clear from the description on page 2, lines 17-20, 28-30, that the following features are essential to the definition of the invention:
(1) plastic details
(2) for removing an electrostatic charge
Since independent claim 1 does not contain these features ((1) and (2)), and since claim 10 does not contain the feature (1), claims 1 and 10 do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.